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Food Labeling; Nutrition Labeling; Guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruit, Vegetables, and Fish; Definition of Substantial Compliance; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0122]

RIN 0905-AB68

Food Labeling: Nutrition Labeling of Raw Fruit, Vegetables, and Fish; Guidelines for Voluntary Nutrition Labeling of Raw Fruit, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed Raw Fruit, Vegetables, and Fish; Definition of Substantial Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is: (1) Identifying the 20 most frequently consumed raw fruit, vegetables, and fish in the United States; (2) establishing guidelines for the voluntary nutrition labeling of these foods; and (3) defining "substantial compliance" with respect to the adherence by food retailers to those guidelines. This action is in response to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: November 8, 1991.

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SUPPLEMENTARY INFORMATION:

I. Background

In response to requirements of the 1990 amendments (Pub. L. 101-535), FDA published in the Federal Register of July 2, 1991 (56 FR 30468) a proposal to identify the 20 most frequently consumed raw fruit, vegetables, and fish in the United States; to establish guidelines for the voluntary nutrition labeling of these foods; and to define "substantial compliance" with respect to the adherence by food retailers to those guidelines. FDA requested comments on these proposed regulations and on the proposed guidelines. Interested persons were given until August 1, 1991 to comment. FDA received approximately 40 responses, each of which contained one or more comments, from trade and retail associations, government organizations, retailers, consumer groups, State groups, private organizations, professional societies, and one university. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., consumer education programs for nutrition labeling) and will not be discussed here. A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follows.

II. Nutrition Labeling of Raw Fruit, Vegetables, and Fish Under the 1990 Amendments

A. Timeframes for Implementation

1. The agency stated in the July 2, 1991 proposal (56 FR 30468 at 30471) that the guidelines for the voluntary nutrition labeling of the 20 most frequently consumed raw fruit, vegetables, and fish, to be issued by November 8, 1991, would be revised, as necessary, after the first report to Congress on retailers, compliance with the voluntary guidelines to reflect other forthcoming labeling regulations. There were requests in several comments that FDA issue all the needed information in its final form for the labeling of raw fruit, vegetables, and fish. Several comments suggested delaying the issuance of the guidelines until the final regulations on serving size, label content, daily intake standards, and label format have been issued. These comments stated that such a delay would allow the agency to develop guidelines for the nutrition labeling of raw fruit, vegetables, and fish that would be consistent with the labeling requirements for processed foods. As a result, it would not be necessary to modify the guidelines when the final rules on those aspects of nutrition labeling are published or to update or replace in-store labeling at that time.

FDA understands the advantages of having all of its regulations that bear on nutrition labeling in place at the time that it issues the guidelines for the nutrition labeling of raw fruit, vegetables, and fish. However, the agency is required by the 1990 amendments to issue these guidelines by November 8, 1991. The guidelines must include information on serving size, label content, daily intake standards (i.e., U.S. Recommended Daily Allowances (U.S. RDA's)), and label format, even though these aspects of the nutrition label are subject to change with the final rules that bear on these matters.

The agency is also required by the 1990 amendments to issue a report to Congress on compliance with the guidelines by retailers by May 8, 1993. This report must be based on actions taken by retailers during the 18 months between November 8, 1991 and May 8, 1993. Realistically, it will take retailers some time after November 8, 1991 before the nutrition labeling programs are in the marketplace, and it will be necessary for the agency to complete its review of the market several months before the report to Congress is due to ensure that the report is submitted on time. Therefore, the time in the marketplace for nutrition labeling of raw produce and fish before assessment of compliance will be closer to 14 to 15 months than 18 months. If the guidelines for nutrition labeling for raw fruit, vegetables, and fish were to be delayed until after the publication of all relevant final regulations (due November 8, 1992), there would be insufficient time to accomplish these tasks and meet the legislative requirement for a report on voluntary compliance by May 8, 1993. Thus, the agency cannot delay issuing the guidelines for the nutrition labeling of raw fruit, vegetables, and fish until the other nutrition labeling regulations are finalized.

2. One comment was concerned with the timeframe for obtaining the labeling data and for providing it in the marketplace. The comment stated that only if FDA can provide the data by November 8, 1991 will there be time for trade associations to distribute it and for retail stores to develop and print the information programs. The comment stated that if the provisions relating to nutrition labeling of raw produce and raw fish are confusing to retailers (because of changes to be made to them), the retailers will not provide the information properly or completely. The comment also noted that the information must be simple and standardized to be useful to consumers. The comment therefore requested that FDA provide the necessary information in final form, with the appropriate serving sizes and in the format desired, before expecting retailers to comply with the regulations.

The agency appreciates these concerns and is providing interim nutrition labeling data for the 60 foods in this final rule (appendices A and B). These data may be used to develop in-store nutrition labeling programs. FDA is providing the data for these foods in serving portions that are generally consistent with the FDA reproposal on serving sizes that is published elsewhere in this issue of the Federal Register. The data in appendices A and B include those that should appear on the label as specified in § 101.45(b) for FDA to find the information to be in compliance. Data are provided for calories, protein, fat, carbohydrate, sodium, and percent

U.S. RDA for vitamin A, vitamin C, calcium, and iron. In addition, data are also provided for the dietary fiber content of fruit and vegetables and for the saturated fat and cholesterol content of fish. The guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish will, however, be subject to change after the first report to Congress by May 8, 1993 to make them consistent with the final rule for Mandatory Nutrition Labeling.

B. Presentation of the Nutrition Information in Retail Stores

There was general support for the flexibility offered by FDA in presenting the nutrition information to the consumer. Several comments noted the importance of presenting the information in a clear, conspicuous, and prominent manner in close proximity to the commodity. One comment stressed that the information must be easily used and understood by consumers.

3. One comment requested that FDA specifically permit the use of more advanced technology, such as electronic signage, for presenting nutrition information.

The language used in § 101.45(a) does not prohibit more advanced technology, and FDA does not think it necessary to specifically provide for its use. Nutrition information should be available to all consumers, and FDA is concerned that information available only on computer screens, TV monitors, or other electronic media might not be available to all when they wish to use it. Mechanical breakdown of equipment, for example, would make the information unavailable. The 1990 amendments suggest that nutrition information presented through video, live demonstration, or other media may be supplementary, but that signs, brochures, notebooks, or leaflets should be the primary means by which nutrition information is presented to consumers.

C. Label Content

4. Comments regarding label content generally supported FDA's proposal. The comments included requests for voluntary declaration of percent U.S. RDA for protein and expressions of support for voluntary declaration of complex carbohydrates and sugars (although one comment argued that the 1990 amendments require that these nutrients be included in the nutrition label); for flexibility in not requiring declaration of nutrients unlikely to be present in a food; for voluntary declaration of dietary fiber for produce; and for voluntary declaration of fatty acids and cholesterol for fish. The comments also included requests to exempt most produce from labeling for calories from fat, saturated fat, cholesterol, complex carbohydrates, and sugars. These requests argued that most raw produce is low in fat, saturated fat, and cholesterol, and that it is costly to analyze these foods for these components. Comments also pointed out that complex carbohydrates are not yet defined, and that raw produce does not contain added sugars. Although several comments agreed that declaration of thiamin, riboflavin, and niacin should be voluntary (56 FR 30468 at 30471), one comment did not agree that information about these nutrients would not add information that is useful to consumers. One comment was against labeling any foods with calories from fat. One comment supported voluntary labeling of omega-3 fatty acids (sum of eicosapentaenoic and docosahexaenoic acids) for fish.

The agency agrees that the inclusion of percent U.S. RDA for protein should be voluntary. While FDA mistakenly failed to state in proposed § 101.45(b)(1) that the inclusion of this information is voluntary (56 FR 30468 at 30482), the examples for nutrition labeling that FDA provided (56 FR 30468 at 30472) did not include the listing of percent U.S. RDA for protein. The codified language in § 101.45(b)(1) now provides that the percent of U.S. RDA for protein, thiamin, riboflavin, and niacin may be voluntarily declared. Declaration of complex carbohydrates, sugars, dietary fiber, saturated fat, and cholesterol are also voluntary under § 101.45(b)(1).

Although not required in the nutrition labeling of raw produce or raw fish, FDA is providing interim data on the dietary fiber content of fruit and vegetables in appendix A and interim data on the saturated fat and cholesterol content of fish in appendix B. These data, which may be used in nutrition labeling of these foods, are provided by FDA because fruit and vegetables are major sources of dietary fiber, fish contain saturated fat and cholesterol, and the levels of these three food components are of interest and importance to consumers.

The mandatory inclusion of calories from fat, saturated fat, cholesterol, complex carbohydrates, sugars, and omega-3 fatty acids on the nutrition label is a label content issue that is outside the scope of this rulemaking. Comments concerning these components should be submitted in response to the agency's supplementary proposal on mandatory nutrition labeling, which is published elsewhere in this issue of the Federal Register.

5. One comment requested that FDA modify the lower level for reporting nutrition labeling values for fish for vitamins A and C, calcium, and iron from 2 percent to 10 percent of the U.S. RDA. The comment stated that fish may contain these nutrients, but that they are not considered important sources. Because the levels of these nutrients are low and variable within some species, the 2 percent cutoff requires costly analysis of fish to be within the technical limits of nutrition labeling.

FDA understands the concern but notes that it is outside the scope of this rulemaking. Comments concerning levels of nutrients in foods and daily values should be submitted in response to the supplementary proposal for mandatory nutrition labeling. The final rule in that proceeding will affect the revision of the guidelines for nutrition labeling of raw fruit, vegetables, and fish. FDA also notes that for consistency of nutrition labeling among all foods, which is necessary to minimize consumer confusion, the lower limits for reporting the nutrient content of foods must not vary among food groups (i.e., the lower limits used for fish should be the same as those used for produce and for processed foods). Finally, FDA believes that it is important for consumers to know which foods can be consumed to increase one's intake, and which foods cannot, of nutrients of public health significance (such as vitamin A, vitamin C, calcium, and iron).

6. One comment stated that carotene, not vitamin A, occurs in fruit and vegetables, and that consumers are aware and knowledgeable of carotene and its role in health. The comment argued that it would be more informative to consumers to label the carotene content (not the vitamin A content) of fruit and vegetables.

FDA believes that this issue is also beyond the scope of this rulemaking. The purpose of this rulemaking is to establish a voluntary program for the nutrition labeling of raw produce and raw fish. The agency believes that such labeling should be consistent for all food products. If this comment is of the opinion that the declaration of vitamin A on the nutrition label should be modified, the comment should be submitted in the mandatory nutrition labeling proceeding. In that rulemaking, FDA is considering under section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) what nutrients should be included in the nutrition label. If the agency concludes that a change is warranted, it will revise the nutrition labeling regulations and the guidelines for the nutrition labeling of raw fruit, vegetables, and fish to reflect that change.

D. Label Format

7. FDA proposed (56 FR 30468 at 30482) that a simplified format may be used for the nutrition labeling of raw fruit, vegetables, and fish. The comments generally supported the use of a simplified label, but those who evaluated it in more detail noted that it only applies to one fruit (apples) and one vegetable (mushrooms). These are the only two of the 60 foods that have more than half of the required nutrients in insignificant amounts. Comments expressed concern about the qualifying statement, "Not a significant source of ____," because FDA uses the term "significant" when referring to 10 percent or more of the U.S. RDA for a comparative claim, and FDA uses the term "insignificant" when referring to values that are less than 2 percent of the U.S. RDA for nutrition labeling. Comments indicated that the qualifying statement could be misinterpreted to mean that the food contained less than 10 percent U.S. RDA rather than less than 2 percent U.S. RDA. One comment requested liberalizing the definition of "significant" for the simplified label to increase its use. Another comment stated that the term "significant source" was not understood by consumers.

Because of the concern expressed about these issues, FDA has decided to remove proposed § 101.45(b)(2) which deals with use of the simplified label and the qualifying statement for the nutrition labeling of raw fruit, vegetables, and fish. FDA notes that there are only nine nutrients that would have to appear in nutrition labeling for raw produce and raw fish for FDA to find the labeling in compliance. Thus, the labels for these foods are already rather simple. After the final rule on mandatory nutrition labeling is in place, and the agency has modified the guidelines to reflect that final rule, FDA will reconsider the use of the simplified format for raw produce and raw fish. The supplementary proposal on mandatory nutrition labeling will address the use of a qualifying statement for nutrition labeling.

E. Serving Sizes

8. Comments expressed support for serving sizes based on portions commonly consumed and agreed that uniformity in serving sizes will be beneficial for shopping comparisons. The comments also agreed with FDA that there was no need for the statement "servings per container" for raw fruit, vegetables, or fish.

As provided in § 101.45(b)(3), information on servings per container need not be included on the nutrition labeling for raw fruit, vegetables, and fish. However, for raw fruit, vegetables, and fish that are sold in packages with multiple serving per package, the retailer may state the number of servings contained in the package.

9. In the proposal in this proceeding, FDA mentioned the serving sizes (56 FR 30468 at 30472) for the nutrition labeling of raw fruit, vegetables, and fish that conformed to the proposed rule for serving sizes (55 FR 29517, July 19, 1990). In Appendices A and B, FDA has provided interim nutrient values for the 20 most frequently consumed raw fruit, vegetables, and fish in serving portions that are generally consistent with the reproposal for the regulation on serving sizes which is published elsewhere in this issue of the **Federal Register.**

The agency's reproposal on serving sizes is based on product category specific reference amounts instead of standard serving sizes. The reproposal lists the following reference amounts for nutrition labeling of raw fruit, vegetables, and fish: 85 grams (g) for fish, 280 g for watermelon, 55 g for fruit used primarily as ingredient (e.g., avocado), 140 g for all other fruit, 30 g for green onion, and 85 g for other vegetables. Because lemons and limes are used primarily for juice and are not eaten whole like other fruit, the serving considered to be appropriate for these fruits are 1 medium lemon (58 g; 2 ounces (oz)) and 1 medium lime (67 g; 2.5 oz), rather that the reference amount of 140 g, which would be closer to 2 lemons or 2 limes.

The reproposal states that serving sizes for products that come in distinct individual units (e.g., apple, orange, or potato) are to be expressed in the number of units that most closely approximate the reference amount, and serving sizes for products that are usually divided for consumption (e.g., cucumber, honeydew melon) are to be expressed in a fraction of the unit that most closely approximates the reference amount. Products in discrete individual units that weigh 67 percent or more, but less than 200 percent, of the reference amount will constitute one serving. However, a whole unit weighing 200 percent or more of the reference amount may be declared as one serving, if the whole unit can reasonably be consumed at a single-eating occasion. Under the reproposal, serving sizes for multi-serving products are required to be expressed in a common household measure that is most appropriate for the specific product. When oz are used as the serving size, an appropriate visual unit of measure, such as a dimension of a piece, is to be provided.

The reproposal specifies that the label statement regarding serving portion is to be the serving size expressed in common household measures followed by the equivalent metric quantity in parentheses. Serving size may be declared in oz in parentheses, following the metric measure where other common household measures are used as the primary unit for serving size (e.g., 1½ cup (138 g) (5 oz)). One oz is defined to weigh 28 g. Ounce measurements are to be expressed in 0.5 oz increments most closely approximating the reference amount.

10. One comment argued that the proposed serving size for fish (i.e., 4 oz) was "unrealistically small." Other comments favored a 1 oz serving for fish so that consumers could multiply the number of oz they eat by the values for 1 oz.

FDA disagrees with the use of a 1 oz serving because it could confuse consumers and is not consistent with "serving size" as defined by the 1990 amendments. The amendments define serving size to be "* * * an amount customarily consumed * * * expressed in a common household measure that is appropriate to the food * * *." In the reproposal for the serving size regulation, the agency is proposing a reference amount for cooked fish (85 g or 3 oz) that is based on the amount of fish customarily consumed as reported in the Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture (USDA). Most comments generally favored a 3 oz portion for fish. They pointed out that a 3 oz serving for fish conforms to the serving used in Seafood Nutri-Facts (Ref. 1), an in-store nutrition labeling program, and that the 1990 amendments directed FDA to take into account the actions taken by food retailers before November 8, 1991, to provide nutrition information on raw agricultural commodities and raw fish to consumers.

11. Several comments requested the use of common household units in addition to, or in place, of g quantities for fruits and vegetables. They stated that consumers would be unfamiliar with the quantity of fruit or vegetable represented by a g weight.

FDA agrees and is allowing for the use of household units (including oz) in addition to the weight of the food in g. The nutrition information provided by FDA for the most frequently consumed raw fruit and vegetables (appendix A) provides the household unit, the weight of a serving in g, and the weight in oz. The nutrition information provided by FDA for the most frequently consumed fish (appendix B) sets forth values that

are for a 3 oz (85 g) portion that has been cooked without fat or seasoning. For several fish (clams, oysters, and scallops), FDA included the number of pieces equivalent to 3 oz.

F. Raw Versus Cooked

12. FDA proposed in § 101.45(b)(5) that nutrition labeling for fruits and vegetables be on a raw basis. Comments generally agreed that nutrient values for fruit and vegetables should be provided on a raw basis, although several comments suggested that values for some vegetables (e.g., potato, sweet corn, sweet potato, green beans, asparagus) should be provided on a cooked basis.

FDA does not agree that nutrition labels for some vegetables should be based on cooked portions because of the need for consistency of labeling within food categories. Therefore, the label values for all fruit and vegetables shall be provided on a raw basis as proposed in § 101.45(b)(5), which is redesignated as § 101.45(b)(4). The values that FDA is presenting in appendix A were derived for fruit and vegetables on a raw basis.

13. FDA proposed in § 101.45(b)(5) that nutritional labeling for fish be on a cooked basis. Several comments argued that all values should be on a raw or as purchased basis to be consistent with the nutrition labeling of the rest of the food supply. However, the majority of the comments on this issue supported using values for fish that are derived on a cooked basis because such values will be most useful to consumers and will prevent the notion that raw fish should be consumed. Several comments argued strongly about the potential for food-borne illness if data were provided for raw fish, and consumers mistook the information as an endorsement for eating raw fish. Several comments noted that the 1990 amendments require that FDA consider programs put in place by retailers, such as the Seafood Nutri-Facts (Ref. 1) which is based on cooked fish. Several comments noted that the label should clearly state that the values are for cooked fish and provide the cooking method or indicate that no fat or seasoning was added. One comment noted that data from analyses of cooked fish are preferred to applying correction factors to data for raw fish.

As provided in proposed § 101.45(b)(5), redesignated as § 101.45(b)(4), FDA continues to believe that nutrient values for fish on a cooked basis (cooked without added fat or seasoning) will be most appropriate under the 1990 amendments because the cooked values are consistent with the nutrient labeling programs that have been developed by retailers for fish, and because cooked values will not encourage the consumption of raw fish. FDA agrees with the comment that the label should state the cooking method used, and, in the nutrition labeling data for fish that FDA has provided in appendix B, the cooking method is stated.

14. One comment noted that the term "cooked without fat or skin" (56 FR 30468 at 30473) was misleading because many fish cannot readily be cooked without their skin (e.g., salmon, trout).

FDA agrees and notes that the nutrient values for fish should be provided on the basis of the cooked, edible portion. The fish need not be cooked without the skin.

G. Nutrient Data

15. There was strong support for the use of single values rather than ranges of values for the nutrition labeling of raw fruit, vegetables, and fish. Comments stated that single values would be more useful and understandable to consumers. One comment suggested that a general statement should be used to indicate to the consumer that nutrient levels vary, and that the values represent averages.

FDA acknowledges that nutrient values for all foods vary. However, the data in appendices A and B on the nutritional labeling of raw fruit, vegetables, and fish reflect nutrient levels for these foods that are available in the United States marketplace, and FDA does not believe that it is necessary to qualify these data. Therefore, FDA is not requiring use of such statements to alert the consumer to nutrient variability. Retailers may optionally use such statements in their brochures, posters, or other methods of displaying the nutrition labeling, if they wish to do so.

16. There was general agreement among the comments that FDA should be responsible for providing the information for the nutrition labeling of raw fruit, vegetables, and fish. The comments also agreed with the use of nutrient values from food composition data bases for the nutrition labeling of these foods. Comments suggested that data from Seafood Nutri-Facts (Ref. 1) and USDA's revised Agriculture Handbook No. 8 might be used for fish and some fruits and vegetables until better data become available. Other comments expressed concern about the lack of reliable data for some fruit, vegetables, and fish and about the cost of generating new data when so many data are already available. One comment suggested that groups or individuals submitting data to FDA for review and evaluation, carefully evaluate and use (if possible) available data and focus new analyses on the foods and nutrients for which information is truly lacking.

Although FDA is not obligated to provide data for the nutrition labeling of the 20 most frequently consumed raw fruit, vegetables, and fish, the agency is providing a chart of interim data (appendices A and B) that retailers may use to initiate their in-store nutrition labeling programs. FDA is providing these data to hasten the development of the in-store programs and the delivery of the information to consumers.

Appendix A lists the 20 most frequently consumed raw fruit and vegetables. The household serving and g and oz edible portion weight of the serving appear below the name of the food. Values are provided for 10 nutrients and food components on a raw basis. Labeling values for 13 fruits (bananas, apples, watermelon, oranges, cantaloupe, grapefruit, strawberries, honeydew melon, avocados, lemons, pineapple, sweet cherries, and kiwifruit) and 17 vegetables (potatoes, iceberg lettuce, tomatoes, onions, carrots, celery, broccoli, green cabbage, cucumbers, bell peppers, cauliflower, leaf lettuce, mushrooms, green beans, radishes, summer squash, and asparagus) were obtained primarily from the Produce Marketing Association (PMA). These values, which were calculated according to the procedures in the FDA manual "Compliance Procedures for Nutrition Labeling" (Ref. 2), were submitted to FDA for review and evaluation. Data for seven fruits (grapes, peaches, pears, nectarines, plums, tangerines, and limes) and three vegetables (sweet corn, sweet potatoes, green onion), which reflect mean values, were derived from USDA Agriculture Handbook No. 8-9 (fruits and fruit juices) (Ref. 3) and No. 8-11 (vegetables and vegetable products) (Ref. 4), and other sources.

Appendix B lists the 20 most frequently consumed raw fish. The serving portion is a 3 oz (85 g) edible portion, cooked. Values are provided for 11 nutrients and food components. The data, which reflect mean values, were derived from Seafood NutriFacts (Ref. 1) (which is based on USDA data), USDA Agriculture Handbook No. 8-15 (finfish and shellfish products) (Ref. 5), and other sources.

FDA stated in the proposal (56 FR 30468 at 30474) that sources of nutrient data for the nutrition labeling of raw fruit, vegetables, and fish could include: (1) Analytical data previously generated by trade associations that were reviewed by FDA and found to be acceptable; (2) data generated from

analyses initiated by retailers, trade associations, or other groups that are submitted to FDA for review and evaluation; and (3) analytical data that have been previously generated by various groups and that are available in the literature, data bases, or elsewhere, which retailers, trade associations, or other groups gather (with appropriate documentation and statistical information) and submit to FDA for review and evaluation.

If FDA does not receive improved data for the seven fruits, the three vegetables, and all 20 fish, the agency will subject the data for these foods that were used in appendices A and B to the FDA compliance calculations and publish the resulting labeling values in the next edition of the charts. As stated in § 101.45(i), which FDA is adding in this final rule to provide for these appendices, FDA intends to revise and publish, with an opportunity for comment, the charts of nutrition labeling data for the 20 most frequently consumed raw fruit, vegetables, and fish at least every 2 years in the Federal Register as new data are derived or received and accepted. This activity will be coordinated with the biennial report to Congress on compliance with voluntary guidelines as long as nutrition labeling of raw produce and fish remains a voluntary activity. The agency has decided not to publish the nutrition labeling values in the CFR at this time because the values are interim and subject to change on a frequent basis. Publication in the CFR may lead to confusion about appropriate values. FDA may wish to reconsider publication in the CFR as newer and better data are submitted to the agency.

17. There was general support for the use of adequately supported and derived composite data. The comments stated that composite data provide a consistent standard for nutrition labeling among stores and a decreased burden for retailers. However, comments also noted that composite labeling could be misleading for some species of fish. For example, one comment noted that composite data for salmon are not specific enough to be useful to consumers because of the differences in fat content among the major species of salmon. The comment suggested that FDA should specify the predominant species of salmon and several other fish listed among the 20 most frequently consumed in the United States.

In response, FDA has identified salmon, mackerel, trout, and crab as encompassing several species with differing nutrient content and has specified in § 101.44(c) the major types of salmon (Atlantic/coho salmon), mackerel (Atlantic/Pacific and jack mackerel), trout (rainbow trout), and crab (blue crab) consumed in the United States (Refs. 6 and 7). The nutrition labeling data in appendix B pertain to these specific types, and the nutrition label should use these specific names.

18. One comment raised a question as to whether attempts could be made to block imports of Canadian produce to the United States on the grounds that their nutrient content was at variance with the nutrition profile generated for produce sold in the United States.

It is not FDA's intention that nutrition labeling be used as a trade barrier. The nutrient data bases generated and accepted for nutrition labeling purposes for raw produce and fish should encompass all products normally consumed in the United States, including imported products. If for some reason a new cultivar of a fruit or vegetable is introduced to the United States, or the levels of importation of fruit or vegetables change, the composite nutrition labeling data should be modified to reflect the change. Nutrition labeling values are expected to change over time to reflect what Americans are consuming. FDA will not attempt to block imports of specific raw fruit, vegetables, and fish to the United States if the nutrient content of these foods does not conform to the composite nutrition labeling data accepted by FDA for these foods.

H. Statistical Treatment of Nutrient Data

19. FDA stated in the July 2, 1991 proposal (56 FR 30468 at 30475–30476) that values for nutrition labeling should be determined according to the procedures outlined in the FDA manual "Compliance Procedures for Nutrition Labeling" (Ref. 2). Several comments expressed a preference for use of mean values for the nutrition labeling of raw fruit, vegetables, and fish rather than the compliance calculations suggested by FDA. There were also comments concerning the confidence intervals of label values based on FDA compliance calculations. Several comments were in favor of current prediction intervals (± 20 percent), while several others offered statistical alternatives to the FDA compliance procedures in the manual.

FDA notes that it is revising its "Compliance Procedures for Nutrition labeling" (Ref. 2), and that some of the concerns expressed about statistical prediction intervals and use of mean values may be resolved with the forthcoming revised manual. FDA requests that data developed for purposes of nutritional labeling conform to the instructions provided in the manual (or subsequent revisions of this manual) for the following reasons:

1. Mean and median values for nutrients and food components do not provide information about the variability of the values. It is not possible, because of space considerations, to put information about standard errors or standard deviations on food labels, and even if it were, the consumer would probably be confused by them. The use of compliance calculations allows the variance to be considered when developing the nutrient values used on food labels. The calculations thus aid the consumer by providing conservative label values in which the consumer can have a high degree of confidence.

2. The use of mean and median nutrient values for nutrition labeling may be misleading. For nutrients that are normally distributed (e.g., have a normal distribution of values around the mean), there is a 50 percent chance that a mean or median value on the label would be above, or below, the actual levels of nutrients in the food. For example, for vitamins, minerals, and protein, there is only a 50 percent chance that if the mean or median values are used for nutrition labeling, they would present the minimum amounts of the nutrient present in a serving of the food. It is equally as likely that the food contains a smaller amount of the nutrient than is declared, as it is that the food contains more of the nutrient. Similarly for calories, cholesterol, fat, and sodium, there is only a 50 percent chance that if the mean or median levels are used for nutrition labeling, they would represent the minimum amount of these substances per serving. Moreover, mean values are influenced by extreme values (e.g., a few outlying values may greatly increase a mean value). The probability that a serving of food will actually contain mean levels of nutrients or food components decreases as the variance increases and as the number of outliers increases. Thus, nutrition labeling values based on mean or median values may provide a low level of confidence.

3. The compliance calculations suggested by FDA give the consumer reasonable assurance that the vitamins, minerals, and protein will be present at levels that are at least 80 percent of label claim, and that calories, fat, cholesterol, and sodium will be present at levels that are no greater than 120 percent of label claim. The use of these calculations is therefore of benefit to the consumer and provides consumer protection.

4. It is important that all foods in the marketplace be labeled consistently. The same procedures that are used for packaged, processed foods should be used for raw produce and for raw fish. The consumer may be confused and deceived by inconsistent labeling of different products. The compliance calculations provided by FDA for nutrition labeling have been recommended and used since 1973.

5. Consumers and nutrition professionals benefit from the improved data bases developed by industry and trade associations and other groups. The use of FDA compliance calculations provides retailers, retail trade associations, and other trade associations with an incentive to continue routine analysis of foods, to analyze more samples, and to improve analytical methods. More analyses (properly done) allow researchers to more clearly define the levels of nutrients in foods and to identify outliers. Often, more analyses lead to a better estimate of the variance or allow the variance to be more clearly defined. As better estimates of the variance of nutrient levels are obtained, the values that can be used for nutrition labeling become more informative.

I. Submission of Data to FDA and Acceptance of Data by FDA

20. There was support for FDA review and evaluation of labeling data submitted to the agency, although one comment, which said that FDA's approach was impractical and burdensome, favored certification of privately generated data bases. One comment requested clarification regarding the submission of data to FDA and the review process for the data. There were several comments related to concerns about inconsistency of data among stores because of several sets of accepted data for a commodity. One comment asserted that approved composite data bases should be made available to all retailers, whether or not they are members of the association developing the data. Another comment asked if FDA will have a system for tracking data, and how the data base will be made available. Another comment asked about acceptance of data sets for wild, as opposed to farmed, fish and species of fish that were more specific than those included in the top 20.

To promote uniformity and consistency of values among stores, FDA is providing in Appendices A and B to this final rule the nutrition labeling data for the 20 most frequently consumed raw fruit, vegetables, and fish. FDA will review and evaluate data that are submitted to the agency for the 20 most frequently consumed raw fruit, vegetables, and fish and for other raw fruit, vegetables, and fish. FDA is providing in § 101.45(i) that, at least every two years, it intends to publish in the **Federal Register**, and to provide an opportunity for comment on, updates of these data sets or a notice that the data sets have not changed from the previous publication. FDA may publish revisions of the data sets more frequently than every two years if better data become available. FDA will keep a log and files of all data submitted and accepted for raw fruit, vegetables, and fish.

FDA will not accept multiple data sets for the nutrition labeling of the 60 commodities. If new data are submitted for a commodity, and FDA judges those data to be superior to previous data, the agency will publish the newer data to replace the old with an opportunity for comment. FDA may decide to replace data for one or more or all nutrient values for a fruit, vegetable, or fish.

As stated in § 101.45(f), accepted data (if not replaced) may be reaccepted by FDA at the end of 10 years. FDA has stated in § 101.45(i) that data accepted by the agency for nutrients other than those listed in appendices A and B for the 20 most frequently consumed raw fruit, vegetables, and fish, and data accepted by FDA for other raw fruit, vegetables, and fish, will be available upon request to FDA (Division of Nutrition, 200 C St. SW., Washington, DC 20204).

J. Identification of the 20 Most Frequently Consumed Raw Fruit, Vegetables, and Fish in the United States

Comments supported a national list (rather than regional lists) for the most frequently consumed raw fruit, vegetables, and fish. There was general support for FDA's definition of "most frequently consumed" and the identification of the foods based on sales, production, and consumption data. Several comments noted a minor misstatement in the proposal (56 FR 30468 at 30476, III.C.1., third paragraph). The statement should have been that the agency has interpreted the phrase "most frequently consumed" to mean those varieties purchased raw (not consumed raw) in the largest quantities by the United States population. FDA does not believe that this minor misstatement had any substantive effect.

21. Several comments wanted a longer list of fish (e.g., 30 rather than 20) to include more species, more regional variation, and a distinction between farmed and wild seafood. As noted previously, one comment wanted salmon to be specified by the predominant type (e.g., Atlantic/coho) because composite nutrient values for all salmon would not be useful to consumers. One comment questioned whether raw, shucked oysters would be included for nutritional labeling. One comment noted that rockfish is a local name in Maryland and Virginia for striped bass and asked for clarification of this fish name for consumers.

Fish that are not among the 20 most frequently consumed may be nutrition labeled. Nutrition labeling data for other fish or for specific varieties of fish that are among the top 20 may be submitted to FDA for review and evaluation or may be used subject to § 101.45(h). FDA does not have sufficient data to provide separate information for farmed and wild fish. However, such data, if available, should be submitted to FDA for review and evaluation and possible acceptance for nutrition labeling. Several of the fish (salmon, mackerel, crab, and trout), identified in the proposal (§ 101.44(c)) as being among the 20 most frequently consumed, have been more specifically defined as Atlantic/coho salmon, Atlantic/Pacific & jack mackerel, blue crab, and rainbow trout. The nutrient values that apply specifically to these species are less variable and, therefore, more useful to consumers. Oysters, which are listed among the 20 most frequently consumed fish, include raw, shucked oysters.

According to FDA's Fish List (Ref. 8), rockfish have many common and regional names, and the term "rockfish" is, indeed, used in some areas for striped bass. FDA hopes that over time, at least in part through nutrition education programs, consistency can be achieved in the names of fish used in retail stores. The fish names listed in appendix B should be used for nutrition labeling at the retail level because these names are accepted nationally and are used by FDA (Ref. 8). FDA believes that it would be misleading to place nutrition labeling data for rockfish under the name of "rockfish" in some areas and under "striped bass" in other areas. Consistency in nutrition labeling of raw produce and fish among stores throughout the United States is essential if the program is to be beneficial to consumers. Consumers may shop in different stores in different areas. They should see the same fish names and nutrition labeling values for the same fish no matter where they shop. Retailers may, if they feel it is necessary, provide clarification to customers about local fish names. Such clarification may be presented as a parenthetical name or a footnote on the

labeling information that is presented in the store. For example, the labeling information might state: "Rockfish (locally known as Striped Bass)."

22. One comment argued that when and where fish are packaged should not be the determining factors in deciding whether fish are to be included in the voluntary labeling program. The comment noted that raw fish may be packaged both by manufacturers and by retailers and asked that there not be different treatment of products identical in species, form, packaging material, and presentation to the consumer. The comment also asked that the definition of fish be extended to include molluscan shellfish and other finfish market cuts such as steaks, chunks, and fillets.

In response to the comment, FDA believes that it is appropriate to clarify which fish, under the 1990 amendments, may voluntarily be labeled and which are required to be nutrition labeled. Fish included under the voluntary nutrition labeling program are: raw (i.e., not heat treated), whole or market cuts of finfish and shellfish; raw, whole, peeled, shelled, or shucked shrimp, scallops, oysters, clams, and lobster; and shelled or unshelled lobster, crab, and shrimp that have been thermally processed. These fish are generally sold in fish stores or in the fresh fish section of grocery stores. They may be frozen or iced. They are generally not packaged or packaged by the retailer in paper or with cellophane and plastic or paperboard tray. Raw, frozen fish that are packaged by a manufacturer (usually in a box with a printed label) and sold in the frozen food case of a grocery store are subject to mandatory nutrition labeling.

K. Substantial Compliance Definition and Determination

23. There was general agreement among comments with the 90 percent compliance requirement for individual stores. There were questions about how the sample of 2,000 stores was derived, and about how representative the sample would be of the United States marketplace. One comment stated that rural America had been overlooked. Several comments feared that the margin of error in the estimation of substantial compliance could over estimate compliance (i.e., that an estimate of 60 percent compliance could really be 56 percent). Several comments said that a chain was 11 or more (not four or more) stores under common ownership.

FDA responds by noting that sample size is study specific and is based on two factors, survey design and desired precision. The survey design incorporates different aspects of the study (in this case, annual sales, proportion of chain versus independent stores, regional variability, and county size) to insure representativeness of the overall population of stores. The desired precision is the degree of certainty of estimates to minimize sampling error.

The selection of a sample of 2,000 stores was based upon the survey design and the assurance that a sample of 2,000 stores provides a relatively narrow margin of uncertainty around an observed compliance level (e.g., a maximum of ± 4 percent for 50 percent compliance and a maximum of ± 3 percent for 60 percent compliance), with an acceptable degree of statistical confidence (95 percent). The percent error decreases as the percent compliance increases. Every estimation of percent compliance has a degree of error; however, the error could be positive or negative. For an identified compliance level of 60 percent and a sample of 2,000, the chances are 95 in 100 that the actual level falls between 56.1 percent and 63.9 percent. Any further increases in sample size are not necessary, because the percentage of further reductions in uncertainty achieved would only be small and diminishing.

Based on the characteristics of the retail grocery distribution system, which were shown in Table 8 of the proposed regulation (56 FR 30468 at 30481) and discussed in the text (56 FR 30468 at 30477), chain versus independent ownership and store volume are key factors in constructing a survey sample that is representative of the total distribution system. Representativeness by rural versus urban areas is further assured by allocating the store sample in proportion to food sales in counties that are highly urbanized, relatively urbanized, rural, and very rural. The specific county size definitions and classifications are based on the 1980 United States census of the population.

Although various definitions of a chain (e.g., 4, 8, or 11 stores under common ownership) are used within the retail food industry, after considering the comments, FDA has decided not to change its definition of a "chain" as four or more stores. This definition is commonly accepted and is used by the major marketing firm that will serve as the contractor for the survey that FDA will undertake to assess compliance with the guidelines.

24. Opinion was divided among the comments about the definition of substantial compliance as "at least 60 percent of all stores that are evaluated in compliance" with the guidelines in § 101.45. Some comments, especially those from retailers and retailer organizations, felt it was appropriate. Others, especially those from consumer groups and professional societies, wanted a higher value of 80 to 90 percent.

FDA understands the concerns of retailers in initiating a new program and the desire of consumer groups to ensure that consumers have access to the information. FDA is concerned that it may take some time to get the programs going and does not want to judge them unfairly, particularly at the onset. As evidenced by the discussion in the preamble to the proposed rule (56 FR 30468 at 30478), FDA carefully considered the statutory criteria for defining "substantial compliance." FDA continues to believe that the criterion that it proposed represents an appropriate balance among the factors that Congress directed it to consider. To meet the 60 percent criterion, well over half of all covered stores will have to provide nutrition labeling. Moreover, if this criterion is met, based on the size and the market share of the stores that FDA will survey, nutrition labeling will be provided for well over half of the sales of raw produce and raw fish in this country. FDA believes that this level of compliance and of providing information to consumers is fairly characterized under the criteria in the law as substantial. Moreover, while the comments that disagreed with FDA's standard asserted that a higher percentage was appropriate, none provided a meaningful basis for a change or demonstrated that FDA's criterion was inconsistent with the act. Therefore, FDA is adopting the standard for "substantial compliance" that it proposed.

25. Several comments requested that substantial compliance be determined separately for raw produce and fish. They stated that the produce section of a store should not be considered to be out of compliance if the fish section did not meet the requirements.

FDA agrees with these comments because of the inherent separateness between the produce industry and the fish industry. The two groups are served, for the most part, by separate retail and trade associations. Also, produce and fish are generally sold in different locations in the grocery stores. FDA believes that the failure to achieve substantial compliance for either produce or fish should not hinder the voluntary nutrition labeling program for the other. FDA has clarified in proposed § 101.43(a) that the raw produce and raw fish in individual stores are to be evaluated separately for compliance and has specified in proposed § 101.43(d)

that substantial compliance is to be evaluated separately for raw produce and for raw fish. FDA will make both evaluations on the basis of samples of 2,000.

Exemptions

26. One comment requested that the exemption for small United States operations be matched by a requirement that United States retailers not pass the labeling responsibility to small volume third country suppliers of produce.

The 1990 amendments specify that it is the responsibility of the retailer, not the supplier, to provide the nutrition labeling information to consumers. In addition, FDA is supplying the necessary interim nutrition labeling information for retailers. Because of these facts, FDA believes that no burden regarding nutrition labeling will fall upon small volume third country suppliers of produce, and, hence, there is no need for an exemption for them.

27. One comment stated that the exemptions specified in the law for small businesses, restaurants, delis, self-service food bars, and foods prepared and processed at the store must be included in the final regulation. One comment felt that FDA should clarify that all raw fruit, vegetables, and fish not within the top 20 are exempt from nutrition labeling. One comment requested clarification that mixtures of fruits and vegetables (e.g., melon cups, fruit salad, vegetable trays with dip, salads) are exempt from labeling requirements. Another comment said that nutrition labeling of minimally processed raw produce packaged with a separate packet of sauce or dressing should be voluntary.

FDA has reviewed the exemptions from nutrition labeling specified in the 1990 amendments as they pertain to the nutrition labeling of raw fruit, vegetables, and fish (56 FR 30468 at 30478). Exemptions from mandatory nutrition labeling of foods are fully covered in the supplementary nutrition labeling proposal.

FDA notes that section 403(q)(5)(A)(ii) of the act provides exemptions from nutrition labeling for food "which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in section 403(q)(5)(A)(i) of the act, and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment." FDA considers in-store prepared packages that contain mixtures of fruit and vegetables (e.g., carrot and celery sticks; slices of mushrooms, green pepper, and cucumber; cantaloupe, honeydew, and watermelon balls; slices of apples, pineapple, and kiwifruit) to be prepared for immediate consumption. They therefore fall within the description offered in section 403(q)(5)(A)(ii) of the act and are exempt from nutrition labeling. Because such products are exempt from nutrition labeling, FDA will not consider them when making determinations of compliance.

Raw fruits or vegetables that are sold with separate packets of sauce or dressing are not included in the voluntary nutrition program. Such products intended for immediate consumption are exempt from nutrition labeling. Such products requiring cooking with the addition of a sauce fall under the requirements for mandatory nutrition labeling.

28. One comment recommended that FDA raise the annual gross sales requirement for small business from $50,000 to $300,000 to assure that small business can avail themselves of this exemption.

The 1990 amendments specify that retailers shall be exempt if they have "annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000 * * *". These legislative values cannot be changed administratively. The values are discussed fully in the supplementary mandatory nutrition labeling proposal.

M. Costs of Program Implementation

29. FDA estimated (56 FR 30468 at 30479) the cost of program implementation to be from $100 to $165 million over 20 years for compliance of at least 60 percent for 99,000 stores. Several comments stated that costs estimated by FDA for the nutrition labeling of raw fruit, vegetables, and fish were conservative because the life of a sign in a grocery store is only 6 months to a year (not 5 years), and because use of an interim program (until the issuance of revised guidelines) will cause the cost of compliance to increase because signs and labels will need to be updated when final regulations and formats are established. Costs were estimated by these comments to be about $150 to $200 per year per store.

FDA has considered the estimates provided by several of the comments and notes that at a yearly cost of $150 for 60 percent compliance, the 20-year cost would be $117 million (at a 5 percent discount rate), and at a yearly cost of $200 for 60 percent compliance, the 20-year cost would be $155 million (at a 5 percent discount rate). FDA is modifying its estimates of the cost of this rule accordingly.

III. Conclusion

In response to comments submitted regarding the proposal for the voluntary nutrition labeling of raw fruit, vegetables, and fish (56 FR 30468), FDA has modified §§ 101.43, 101.44, and 101.45. The agency has adopted the provisions of § 101.42 and other parts of §§ 101.43 through 101.45 as proposed because the agency did not receive any comments concerning them or because, as explained above, the comments received did not provide any basis to justify a change. The following summarizes the changes being made to §§ 101.43 through 101.45 by this final rule:

FDA has modified § 101.42(e) and (f) and § 101.43(a) to clarify that substantial compliance will be assessed separately for raw agricultural commodities (i.e., raw fruit and vegetables) and for raw fish.

In § 101.43(b), FDA has changed the phrase "* * * raw fruit, vegetables, and fish * * *" to "* * * raw fruit and vegetables and of raw fish * * *" to clarify that substantial compliance will be assessed separately for raw agricultural commodities and for raw fish.

As discussed above, section 101.43(d) is being added and states "FDA will evaluate substantial compliance separately for raw agricultural commodities and for raw fish."

In § 101.44(c), the types of salmon, mackerel, crab, and trout that are among the 20 most frequently consumed raw fish are being more precisely identified, so that the nutrient values will be of greater use to consumers. These fish are now being described as Atlantic/coho salmon, Atlantic/Pacific and jack mackerel, blue crab, and rainbow trout.

In § 101.45(b)(1), as explained above, FDA is changing the statement "Thiamin, riboflavin, and niacin may be declared in the nutrition labeling" to "The percent U.S. RDA for protein, thiamin, riboflavin, and niacin may be declared in the nutrition labeling." A statement has been added that declaration of complex carbohydrates, sugars, dietary fiber, saturated fat, and cholesterol is voluntary.

As explained above, proposed § 101.45(b)(2), which concerned the use of a simplified label and a qualifying statement, has been removed. Sections 101.45(b)(3) through (b)(5) have been redesignated as § 101.45(b)(2) through (b)(4).

In redesignated § 101.45(b)(2), in the first sentence of this paragraph, the phrase "for the full or simplified formats" is being removed because the discussion about the simplified format has been removed.

In § 101.45(e), in the first sentence, the word "booklet" is being replaced by "manual" to be consistent with the text of the **Federal Register**. The phrase "(or subsequent revisions of this manual)" is being inserted after the name of the manual. In the second sentence, the word "It" was replaced by "The manual" for clarification.

In § 101.45(f), in the first sentence, the phrase "* * * of the data base * * *" is being replaced by "* * * of a submitted data base * * *" for clarification.

In § 101.45(f), the following is being added to the end of the second sentence, "* * * or until another data base on the same commodity is submitted to FDA and found to be superior." In addition, in § 101.45(f), in the fourth sentence, the following is being inserted after "unless," "* * * the data base is being superseded by another on the same commodity or * * *." These changes reflect the fact that, as discussed above, FDA will not accept multiple data sets but will only maintain the best data available.

In § 101.45(h), the word "raw" is being inserted before "fruit" for clarification.

As discussed above, section 101.45(i) is being added. This new section states: "FDA will publish, and provide an opportunity for comment on, updates of the nutrition labeling data for the 20 most frequently consumed raw fruit, vegetables, and fish (or a notice that the data sets have not changed from the previous publication) at least every 2 years in the **Federal Register**. FDA accepted data for other raw fruit, vegetables, and fish or for other nutrients are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204."

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**.

The costs of compliance with this final rule alone are discussed in section II.M. above. FDA has estimated the costs that may be incurred as a result of the provisions of the 1990 amendments covered by this final rule to be between $117 million to $155 million. FDA welcomes comments on these cost estimates.

VI. References

1. "Seafood Nutri-Facts," Fresh Seafood Nutrition Information Program, developed by the Food Marketing Institute and the National Fisheries Institute, Washington, DC, 1988.

2. Division of Mathematics, Center for Food Safety and Applied Nutrition, FDA, "Compliance Procedures for Nutrition Labeling," Washington, DC, 1973.

3. "Composition of Foods—Raw, Processed, Prepared, Fruits and Fruit Juices," Agriculture Handbook No. 8-9, USDA, Human Nutrition Information Service, Washington, DC, 1982.

4. "Composition of Foods—Raw, Processed, Prepared, Vegetables and Vegetable Products," Agriculture Handbook No. 8-11, USDA, Human Nutrition Information Service, Washington, DC, 1984.

5. Composition of Foods—Raw, Processed, Prepared, Finfish and Shellfish Products," Agriculture Handbook No. 8-15, USDA, Human Nutrition Information Service, Washington, DC, 1987.

6. National Fisheries Institute, data on fish production, provided to FDA, Washington, DC, letter dated January 4, 1991.

7. Personal communication, L. Weddig, National Fisheries Institute, Inc., August 15, 1991.

8. The Fish List, FDA Guide to Acceptable Market Names for Food Fish Sold in Interstate Commerce, Superintendent of Documents, U.S. Government Printing Office, Washington, DC, 1988.

VII.—Appendix A

[Nutritional labeling accepted by FDA for the 20 most freguently consumed raw fruit and vegetables (August 1991).]

Fruit (Edible portion weight)	Kilocalories	Protein (g)	Carbohydrates (g)	Fat (g)	Dietary Fiber (g)	Sodium (mg)	Percent U.S. RDA			
							Vitamin A	Vitamin C	Calcium	Iron
Banana, raw, 1 medium, (126 g) (4.5 oz)	120	1	28	1	3	0	(1)	15	(1)	2
Apple, raw, 1 medium, (154 g) (5.5 oz)	80	0	18	1	5	0	(1)	6	(1)	(1)
Watermelon, raw, 1/16 medium melon; 2 cups diced pieces (280 g) (10 oz)	80	1	19	0	1	10	8	25	(1)	2
Orange, raw, 1 medium, (154 g) (5.5 oz)	50	1	13	0	6	0	(1)	120	4	(1)
Cantaloupe, raw, ¼ medium melon, (134 g) (5 oz)	50	1	11	0	0	35	80	90	2	2
Grape, raw, 1½ cups, (138 g) (5 oz)	85	1	24	0	2	3	3	9	2	2
Grapefruit, raw, ½ medium, (154 g) (5.5 oz)	50	1	14	0	6	0	6	90	4	(1)
Strawberry, raw, 8 medium, (147 g) (5.5 oz)	50	1	13	0	3	0	(1)	140	2	2
Peach, raw, 2 medium, (174 g) (6 oz)	70	1	19	0	1	0	20	20	(1)	(1)
Pear, raw, 1 medium, (166 g) (6 oz)	100	1	25	1	4	1	(1)	10	2	2
Nectarine, raw, 1 medium, (140 g) (5 oz)	70	1	16	1	3	0	20	10	(1)	(1)
Honeydew melon, raw, 1/10 medium melon, (134 g) (5 oz)	50	1	12	0	1	50	(1)	40	(1)	2
Plum, raw, 2 medium, (132 g) (4.5 oz)	70	1	17	1	1	0	9	20	(1)	(1)
Avocado, raw, ⅓ medium, (55 g) (2 oz)	120	1	3	12	2	5	(1)	5	(1)	(1)
Lemon, raw, 1 medium, (58 g) (2 oz)	18	0	4	0	0	10	(1)	35	2	(1)
Pineapple, raw, 2 slices, 3" diameter, ¾" thick, (112 g) (4 oz)	90	1	21	1	2	10	(1)	35	(1)	(1)
Tangerine, raw, 2 medium, 2⅜" diameter (168 g) (6 oz)	70	1	19	0	2	2	30	85	2	(1)
Sweet cherry, raw, 21 cherries; 1 cup, (140 g) (5 oz)	90	1	19	1	3	0	(1)	10	2	(1)
Kiwifruit, raw, 2 medium, (148 g) (5.5 oz)	90	1	18	1	4	0	2	230	4	4
Lime, raw, 1 medium, (67 g) (2.5 oz)	20	0	7	0	3	1	(1)	35	2	2
Potato, raw, 1 medium, (148 g) (5.5 oz)	110	3	23	0	3	10	(1)	50	(1)	8
Iceberg lettuce, raw, ⅛ medium head, (89 g) (3 oz)	20	1	4	0	1	10	2	4	(1)	(1)

VII.—APPENDIX A—Continued

[Nutritional labeling accepted by FDA for the 20 most freguently consumed raw fruit and vegetables (August 1991).]

Fruit (Edible portion weight)	Kilocalories	Protein (g)	Carbohydrates (g)	Fat (g)	Dietary Fiber (g)	Sodium (mg)	Percent U.S. RDA			
							Vitamin A	Vitamin C	Calcium	Iron
Tomato, raw, 1 medium, (148 g) (5.5 oz)	35	1	6	1	1	10	20	40	(1)	2
Onion, raw, 1 medium, (148 g) (5.5 oz)	60	1	14	0	3	10	(1)	20	4	(1)
Carrot, raw, 7" long, 1¼" diameter (78 g) (3 oz)	40	1	8	1	1	40	330	8	2	(1)
Celery, raw, 2 medium stalks (110 g) (4 oz)	20	1	4	0	2	140	(1)	15	4	(1)
Sweet corn, raw, kernels from, 1 medium ear (90 g) (3 oz)	75	3	17	1	1	15	5	10	(1)	3
Broccoli, raw, 1 medium stalk, (148 g) (5.5 oz)	40	5	4	1	5	75	10	240	6	4
Green cabbage, raw, 1/12 medium head (84 g) (3 oz)	18	1	3	0	2	30	(1)	70	4	(1)
Cucumber, raw, ⅓ medium, (99 g) (3.5 oz)	18	1	3	0	0	0	4	6	2	2
Bell pepper, raw, 1 medium, (148 g) (5.5 oz)	25	1	5	1	2	0	2	130	(1)	(1)
Cauliflower, raw, ⅛ medium head (99 g) (3 oz)	18	2	3	0	2	45	(1)	110	2	2
Leaf lettuce, raw, 1.5 cup shredded (85 g) (3 oz)	12	1	1	0	1	40	20	4	4	(1)
Sweet potato, raw, medium, 5" long, 2" diameter (130 g) (4.5 oz)	140	2	32	0	3	15	520	50	3	4
Mushroom, raw, 5 medium, (84 g) (3 oz)	25	3	3	0	0	0	(1)	2	(1)	(1)
Green onion, raw, ¼ cup chopped (25 g) (1 oz)	7	0	1	0	0	0	3	20	(1)	5
Green (snap) bean, raw, ¾ cup cut (83 g) (3 oz)	14	1	2	0	3	0	2	8	4	(1)
Radish, raw, 7 radishes (85 g) (3 oz)	20	0	3	0	0	35	(1)	30	(1)	(1)
Summer squash, raw, ½ medium, (98 g) (3.5 oz)	20	1	3	0	1	0	4	25	2	2
Asparagus, raw, 5 spears (93 g) (3.5 oz)	18	2	2	0	2	0	10	10	(1)	(1)

[1] Less than 2% U.S. RDA.

Notes

Data sources:

Produce Marketing Association (all data except as noted below).

USDA Revised Agriculture Handbook No 8–9 (Fruits and Fruit Juices, 1982) and 8–11 (Vegetables and Vegetable Products, 1984) for grape, peach, pear, nectarine, plum, tangerine, lime, sweet corn, sweet potato, and green onion; dietary fiber for pineapple, tomato, and carrot; dietary fiber for grape and plum based on similar foods.

Dietary fiber for nectarine, tangerine, lime, and green onion from *McCance and Widdowson's The Composition of Foods* by A.A. Paul and D.A.T. Southgate, 4th revised ed., Elsevier/North-Holland Biomedical Press, NY, 1978 or *Nutrient Content of Food Portions* by J. Davies and J. Dickerson, The Royal Society of Chemistry, Cambridge, U.K., 1991.

Serving portion weights in oz from PMA were multiplied by 28 to obtain g weights; 55 g were used for 2 oz, and 85 g were used for 3 oz. Ounces were rounded to the nearest 0.5 oz for the chart. Serving portions weights in g from USDA were divided by 28 to obtain oz; oz were rounded to the nearest 0.5 oz.

Values were rounded in accordance with 21 CFR 101.9. Percent U.S. RDA was based on 5,000 IU for vitamin A, 60 milligrams (mg) for vitamin C, 1,000 mg for calcium, and 18 mg for iron.

Avocado data were derived from two data sets and are based on California varieties.

VIII. APPENDIX B

[Nutrition labeling accepted by FDA for the 20 most frequently consumed fish (August 1991)]

	Kilocalories	Protein (g)	Carbohydrates (g)	Fat (g)	Saturated Fatty Acid (g)	Cholesterol (mg)	Sodium (mg)	Percent U.S. RDA			
								Vitamin A	Vitamin C	Calcium	Iron
Fish, 3 oz edible portion, cooked [2]											
Shrimp, boiled	110	22	0	2	0	160	155	(1)	3	3	15
Cod, broiled, skinless	90	19	0	1	0	50	60	(1)	2	(1)	2
Pollack, broiled, skinless	100	21	0	1	0	80	90	(1)	(1)	(1)	(1)
Catfish, baked, skinless	120	19	0	5	1	60	65	(1)	(1)	3	5
Scallop, broiled, 5.7 large or 14 small	150	26	0	1	0	60	275	(1)	3	2	(1)
Salmon, Atlantic/coho, baked, skinless	150	22	0	7	1	50	50	(1)	2	(1)	4
Flounder, baked, skinless	100	20	0	1	0	50	85	(1)	(1)	2	2
Sole, broiled, skinless	100	21	0	1	0	60	90	(1)	(1)	2	2
Oyster, steamed, 12 medium	120	12	0	4	1	90	190	(1)	(1)	8	65
Orange roughy, broiled, skinless	130	16	0	7	0	20	70	(1)	(1)	(1)	(1)
Mackerel, Atlantic/Pacific & jack, broiled, skinless	190	21	0	12	3	60	95	7	(1)	(1)	9
Ocean perch, baked, skinless	100	20	0	2	0	50	80	(1)	(1)	10	6
Rockfish, baked, skinless	100	20	0	2	0	40	65	4	(1)	(1)	3
Whiting, baked, skinless	100	19	0	1	0	70	75	2	(1)	5	2
Clam, steamed, 12 small	130	22	0	2	0	60	95	10	(1)	8	130
Haddock, baked, skinless	90	20	0	1	0	60	70	(1)	(1)	4	6
Blue crab, steamed	90	19	0	1	0	80	310	(1)	(1)	9	4
Rainbow trout, broiled, skinless	130	22	0	4	1	60	30	(1)	5	7	10
Halibut, broiled, skinless	120	22	0	2	0	30	60	3	(1)	5	5
Lobster, boiled	100	20	0	1	0	100	320	(1)	(1)	5	2

[1] Less than 2% U.S. RDA.
[2] Cooked without fat or seasoning.

Notes

Data sources:

Seafood Nutri-Facts by the Food Marketing Institute and the National Fisheries Institute, 1988 (all values except vitamin A, vitamin C, calcium, iron).

USDA Agriculture Handbook No. 8-15 (Finfish and Shellfish Products, 1987) and NOAA (National Oceanic and Atmospheric Administration) Technical Memo NMFS F/SEC-11 (1981) (vitamin A, vitamin C, calcium, iron).

([1]) = assumed less than 2 U.S. RDA (no data available).

Atlantic/coho salmon was selected for labeling because most pink salmon is canned, and most sockeye salmon is exported to Japan. Atlantic/Pacific and jack mackerel were selected for labeling because consumption of Spanish mackerel is low. Personal communication with L. Weddig of National Fisheries Institute, August 15, 1991.

Nutrient values were averaged for Atlantic and coho salmon and for Atlantic and Pacific and jack mackerel.

Atlantic cod was used for cholesterol and sodium; Pacific cod would be 40 mg cholesterol and 75 mg sodium.

Values were rounded in accordance with 21 CFR 101.9. Percent U.S. RDA was based on 5,000 IU for vitamin A, 60 mg for vitamin C, 1,000 mg for calcium, and 18 mg for iron.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Subpart C is added to read as follows:

Subpart C—Specific Nutrition Labeling Requirements and Guidelines

Sec.

Subpart C—Specific Nutrition Labeling Requirements and Guidelines

§ 101.42 Nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) urges food retailers to provide nutrition information, as provided in § 101.9(c), for raw fruit, vegetables, and fish at the point-of-purchase. If retailers choose to provide such information, they should do so in a manner that conforms to the guidelines in § 101.45.

(b) In § 101.44, FDA has listed the 20 varieties of raw fruit, vegetables, and fish that are most frequently consumed during a year and to which the guidelines apply.

(c) FDA has also defined in § 101.43, the circumstances that constitute substantial compliance by food retailers with the guidelines.

(d) By May 8, 1993, FDA will issue a report on actions taken by food retailers to provide consumers with nutrition information for raw fruit, vegetables, and fish under the guidelines established in § 101.45.

(1) The report will include a determination of whether there is substantial compliance, as defined in § 101.43, with the guidelines.

(2) In evaluating substantial compliance, FDA will consider only the 20 varieties of raw fruit, vegetables, and fish most frequently consumed as identified in § 101.44.

(e) If FDA finds that there is substantial compliance with the guidelines for the nutrition labeling of raw fruit and vegetables or of fish, the agency will so state in the report, and the guidelines will remain in effect. FDA will reevaluate the market place for substantial compliance every 2 years.

(f) If FDA determines that there is not substantial compliance with the guidelines for raw fruit and vegetables or for raw fish, the agency will at that time issue proposed regulations requiring that any person who offers raw fruit and vegetables or fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by § 101.9. Final regulations would have to be issued 6 months after issuance of proposed regulations, and they would become effective 6 months after the date of their promulgation.

§ 101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) will judge a food retailer who sells raw agricultural commodities or raw fish to be in compliance with the guidelines in § 101.45 with respect to raw agricultural commodities if the retailer displays or provides nutrition labeling for at least 90 percent of the raw agricultural commodities listed in § 101.44 that it sells, and with respect to raw fish if the retailer displays or provides nutrition labeling for at least 90 percent of the types of raw fish listed in § 101.44 that it sells. To be in compliance, the nutrition labeling shall:

(1) Be presented in the store or other type of establishment in a manner that is consistent with § 101.45(a);

(2) Be presented in content and format that are consistent with § 101.45(b); and

(3) Include data that have been provided by FDA (see § 101.45(i)), that have been accepted by FDA (see § 101.45 (c), (f), and (g)), or that are consistent with § 101.45 (d) and (e) and have not been found to be out of compliance after a review under § 101.9(e) (see § 101.45(h)).

(b) To determine whether there is substantial compliance by food retailers with the guidelines in § 101.45 for the voluntary nutrition labeling of raw fruit and vegetables and of raw fish, FDA will select a representative sample of 2,000 stores, allocated by store type and size, for raw fruit and vegetables and for raw fish.

(c) FDA will find that there is substantial compliance with the guidelines in § 101.45 if it finds based o paragraph (a) of this section that at least 60 percent of all stores that are evaluated are in compliance.

(d) FDA will evaluate substantial compliance separately for raw agricultural commodities and for raw fish.

§ 101.44 Identification of the 20 most frequently consumed raw fruit, vegetables, and fish in the United States.

(a) The 20 most frequently consumed raw fruit are: Banana, apple, watermelon, orange, cantaloupe, grape, grapefruit, strawberry, peach, pear, nectarine, honeydew melon, plum, avocado, lemon, pineapple, tangerine, sweet cherry, kiwifruit, and lime.

(b) The 20 most frequently consumed raw vegetables are: Potato, iceberg lettuce, tomato, onion, carrot, celery, sweet corn, broccoli, green cabbage, cucumber, bell pepper, cauliflower, leaf lettuce, sweet potato, mushroom, green onion, green (snap) bean, radish, summer squash, and asparagus.

(c) The 20 most frequently consumed raw fish are: Shrimp, cod, pollack, catfish, scallop, Atlantic/coho salmon, flounder, sole, oyster, orange roughy, Atlantic/Pacific and jack mackerel, ocean perch, rockfish, whiting, clam,

haddock, blue crab, rainbow trout, halibut, and lobster.

§ 101.45 Guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

Nutrition labeling for raw fruit, vegetables, and fish listed in § 101.44 should be presented to the public in the following manner:

(a) Nutrition labeling information should be displayed at the point of purchase by an appropriate means, including by affixing it to the food, by posting a sign, or by making the information readily available in brochure, notebook, or leaflet form in close proximity to the foods. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) Nutrition information should be provided on the label or in labeling in accordance with § 101.9, as modified by the following guidelines:

(1) The percent U.S. RDA for protein, thiamin, riboflavin, and niacin may be declared in the nutrition labeling. Declaration of complex carbohydrates, sugars, dietary fiber, saturated fat, and cholesterol is also voluntary.

(2) Nutrition labeling information may be presented on individual labels or in charts in vertical columns or in lines. When lines are used, any subcomponents declared should be listed parenthetically after principal components (e.g., saturated fat should be parenthetically listed after fat).

(3) Declaration of the number of servings per container need not be included in nutrition labeling of raw fruit, vegetables, and fish.

(4) The nutrition label data should be based on raw edible portion for fruit and vegetables and on a cooked edible portion for fish. The methods used to cook fish should be those that do not add fat, breading, or seasoning (e.g., salt or spices).

(c) Nutrient data and proposed nutrient values for nutrition labeling for raw fruit, vegetables, and fish may be submitted to the Division of Nutrition (HFF-260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, for review and evaluation. The data and nutrient values for nutrition labeling are appropriate for use if they are accepted by the Food and Drug Administration (FDA). The submission to FDA should include information on the source of the data (names of investigators, name of organization, place of analysis, dates of analyses), number of samples, sampling scheme, analytical methods, statistical treatment of the data, and proposed quantitative label declarations. The nutrient values for the nutrition labeling should be determined in accordance with FDA guidance.

(d) Composite data that reflect representative nutrient levels for various varieties, species, cultivars; seasons; and geographic regions may be used to label raw fruit, vegetables, and fish. Alternatively, data that reflect a specific variety, species, cultivar; season; or geographic region may be used to label raw fruit, vegetables, and fish; the nutrition labeling information for such variety, etc., should provide food names and descriptions for the fruit, vegetables, and fish that appropriately reflect the samples analyzed for nutrient values.

(e) The FDA manual "Compliance Procedures for Nutrition Labeling" (or subsequent revisions of this manual) should be used to develop nutrition label values from data base values. The manual is available from the Division of Nutrition.

(f) If the agency's Center for Food Safety and Applied Nutrition agrees to all aspects of a submitted data base, FDA will notify a submitter in writing of its acceptance of the nutrient data and nutrient values for nutrition labeling. FDA's acceptance will be for a period of 10 years or until other data for the same food are submitted to FDA and found to be superior. Those obtaining data base and nutrient value acceptance from FDA are responsible for continued maintenance of the data base. FDA will renew its acceptance of a data base upon request after 10 years unless the data have been superseded by other data on the same food or there have been demonstrated changes in agricultural or industry practices. When agricultural or industry practices change (e.g., a change occurs in a predominant variety produced), or when FDA monitoring suggests that the data base or nutrient values are no longer representative of the item sold in this country, FDA will take steps to revoke its acceptance of the data base and nutrient values. A revised data base and proposed nutrient values may be submitted to FDA for acceptance.

(g) If the nutrition information is in accordance with an FDA-accepted data base, the nutrient values have been computed following FDA guidelines, and the food has been handled in accordance with current good manufacturing practices to prevent nutrient loss, a nutrition label will not be subject to the agency compliance review under § 101.9(e).

(h) Organizations may use data bases that they believe validly reflect the nutrient content of raw fruit, vegetables, and fish; however, labeling computed from data bases not reviewed, evaluated, and accepted by the agency is subject to the compliance procedures of § 101.9(e).

(i) FDA will publish, and provide an opportunity for comment on, updates of the nutrition labeling data for the 20 most frequently consumed raw fruit, vegetables, and fish (or a notice that the data sets have not changed from the previous publication) at least every 2 years in the **Federal Register**. FDA accepted data for other raw fruit, vegetables, and fish, or for other nutrients, are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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